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10/623,432	07/17/2003	Gary A. Strobel	34373/0007	4064

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1530 Drew Avenue
Davis, CA 95618

EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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09/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/623,432	Applicant(s) STROBEL ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 90-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 90-100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed 7/5/07 is acknowledged. Claims 90-100 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 90-100 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for using a composition as recited in claim 90 wherein the one or more volatile organic compounds comprises isobutyric acid at a relative ratio of at least about 5%, and the isobutyric acid is present in the locus at a concentration of less than 2800 ppm. It is noted that the recitations "relative ratio" and "at least about 5%" do not clearly set forth the concentrations intended. In addition, "at least about 5%" and "less than 2800 ppm" for the same compound, i.e., isobutyric acid appear contradictory and inconsistent in this context.

No basis or support is found in the present specification for using a composition as recited in claim 98 wherein the one or more volatile organic comprises isobutyric acid at a relative ratio of at least about 5%, and the isobutyric acid is present in the locus at a concentration of less than 2800 ppm and further comprises 2-methyl-1-butanol "at a relative ratio of at least about 25% and wherein the 2-methyl-1-butanol is present in the locus at a concentration less than 2500 ppm" or "3-methyl-1-butanol at a relative ratio of at least about 25%".

No basis or support is found in the present specification for using a composition as recited in claims 99 or 100 wherein the composition used in claim 98, further comprises isobutyl alcohol at a relative ratio of at least about 5%, respectively, further comprises ethyl butyrate at a relative ratio of at least about 25%

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Applicant has not indicated with any particularity the source in the as-filed written disclosure for the values now recited or how they relate specifically to “an effective amount”. In this regard at least claims 90 and 98 appear contradictory and inconsistent in requiring “a relative ratio of **at least about 5%**” (50 g/l), for example, without an indication what this percentage is relative to, or whether it is 5% by weight or volume and simultaneously requiring a concentration of **less than 2800 ppm** (2.8 g/l or .28%) without an indication of what the “parts” pertain to. The same issues pertain to claim 98.

Therefore, this material constitutes new matter and should be deleted.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant has cited the tables as providing support for the amounts recited. However, no clear correlation is seen between the values recited in the tables and the invention as claimed. There nothing in the tables that recited that isobutyric acid is at a relative ratio of at least about 5%, and the isobutyric acid is present in the locus at a concentration of less than 2800 ppm and that the composition further comprises 2-methyl-1-butanol “at a relative ratio of at least about 25% and wherein the 2-methyl-1-butanol is present in the locus at a concentration less than 2500 ppm” or “3-methyl-1-butanol at a relative ratio of at least about 25%”. Similarly there is nothing in the tables that recites compositions that further comprise isobutyl alcohol at a relative ratio of at least about 5%, respectively, or further comprises ethyl butyrate at a relative ratio of at least about 25%. The phrase “at least about” does not set forth with any particularity the amount intended. This recitation may mean “about 5% to about 100%” or “4%-100%”, or “5.9%-100%”, or “3.5%-100%”. No basis or support is found for any of these various interpretations of “at least about” for these relative ratios having no clear dimensions or other components.

Therefore the rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 90-100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 90 is vague, indefinite and confusing regarding the use of a composition wherein the one or more volatile organic compounds comprises isobutyric acid at a relative ratio of at least about 5%, and the isobutyric acid is present in the locus at a concentration of less than 2800 ppm. It is noted that the recitations "relative ratio" and "**at least about 5%**" do not clearly set forth the concentrations intended, i.e., whether the percentage is by weight or volume and what the "relative" pertains to. In this regard at least claims 90 and 98 appear contradictory and inconsistent in requiring "a relative ratio of **at least about 5%**" (50 g/l), for example, without an indication what this percentage is relative to, or whether it is 5% by weight or volume and simultaneously requiring a concentration of **less than 2800 ppm** (2.8 g/l or .28%) without an indication of what the "parts" pertain to. The same issues pertain to claim 98.

Thus, the claims appear contradictory and inconsistent in this context, even when reading the claim in light of the specification. See, also the new matter rejection *supra*.

The claims as written fail to clarify what is intended to be an "effective amount" in this context.

Claim 95 is incorrect in that *Rhizoctonia solani* is not a bacterium.

Claim 96 is confusing in the recitation of "the fungus is from". Deletion of "from" would be remedial.

Claims 90-92 and 95-100 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the inhibition of certain bacteria or fungi with a mixture of volatile compounds does not reasonably provide enablement for the inhibition of any bacteria or fungi that contaminate buildings using certain volatiles singly or in combination in the amounts recited.

The inhibition of bacteria and fungi with volatile compounds is unpredictable particularly when using trace amounts in a composition. The specification as-filed does not provide sufficient guidelines or teachings for the inhibition of any and all bacteria or fungi that contaminate any food container or buildings as claimed. The size of the "container" cannot be

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ascertained. It is noted that large, room size "containers" are placed on ships. Post harvest food includes fruit, vegetables, fish, shellfish and dairy products. It is noted that some of the volatiles listed are toxic. The teachings provided in the as-filed specification would not have enabled one skilled in the art to "use" the recited volatile compounds to inhibit any bacteria or fungi that contaminate post harvest food containers or buildings, in the claim designated methods. The guidance provided in the specification is not adequate to lead persons of skill in the art toward success in inhibiting all the organisms recited in the process encompassed by the claims in a predictable manner, because the effects of single compounds are not set forth with any particularity and the amounts required for effectiveness are not specified with sufficient particularity. It is apparent that applicant is offering an "invitation to experiment" to those skilled in the art to perform various techniques and to determine for themselves whether they have inhibited the growth of a microbe, insect or nematode. See *Genentech, Inc. v Novo Nordisk A/S*, 42 USPQ2d, 1001, 1005 (Fed. Cir. 1997) ("Tossing out the mere germ of an idea does not constitute an enabling disclosure"). Also, *In re Scarbrough*, 182 USPQ 298, 302 (CCPA 1974) ("It is not enough that a person skilled in the art, by carrying out investigations along the line indicated in the instant application, and by a great amount of work eventually might find out how to make and use the instant invention. The statute requires the application itself to inform, not to direct others to find out for themselves. *In re Gardner et al.*, 166 USPQ 138 (1970)").

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary to identify the volatile compound(s) necessary to inhibit the growth of any and all bacteria or fungi that contaminate post harvest food containers or buildings as recited; limited amount of guidance and limited number of working examples in the specification directed to the treatment of a large variety of members of the organisms recited with combinations of compounds; the unpredictable nature of an invention directed to the use of single or specific combinations of volatile compounds in any amount to inhibit the growth of any and all any bacteria or fungi that contaminate post harvest food containers or buildings; the unpredictability in the art and breadth of the claims directed to the use of certain volatiles singly or in certain combinations to inhibit the growth of any and all any bacteria or fungi that

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contaminate post harvest food or buildings. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Response to Arguments

Applicant's arguments and Mercier declaration have been fully considered but they are not deemed to be persuasive.

The Mercier declaration addresses the control *in vitro* of certain fungi, none of which are clearly known to contaminate buildings. Even to the extent that *Aspergillus niger* can be considered to "contaminate" buildings, the results of page 2, C. cannot be correlated to a method of treating a building with an effective amount of the recited volatiles and the confusing amounts recited.

Applicant presents data to show experiments against specific fungi and one bacterium in specific Petri dish environments, all of which appear to be sealed and wherein post-harvest pathogens in plants using fumigation boxes wherein the microbes are treated with the volatile for extended period of time.. However the claims are directed to the inhibition of growth of in a closed environment of any bacteria or fungi that contaminate post harvest food or buildings. The data presented in the declaration are directed to the inhibition of growth of the few fungi and one bacterium, specifically *Penicillium expansum*, *Rhizoctonia solani*, *Aspergillus niger*, *Geotrichum citri-aurantii*, *Erwinia carotorova* and *Cladosporium cladosporioides*. While results are impressive, these findings cannot be properly extrapolated to any and all any bacteria or fungi that contaminate post harvest food or buildings. It is well known that at least some of the touted volatiles are produced by microbes, the growth of which is clearly not inhibited thereby, particularly in amounts that encompass the absence of volatiles. For example, Nout adequately demonstrate that a mixture of volatiles comprising 3-methyl-1-butanol and/or 2-methyl-1-butanol are ineffective to inhibit the growth of microbes such as *P. kluyveri*, *C. shehatae*, *C. zeylanoides*, *C. guilliermondi* and *D. hanseii*. See, e.g., Tables 1-3. In addition. Robinson *et al.* adequately demonstrate that exposure to a mixture of volatiles comprising isobutanol does not affect the growth of a fungus such as *Fusarium oxysporum*. See, e.g., Table 1. At least *P. kluyveri* and *Fusarium oxysporum* are post harvest pathogens.

Thus, the scope of the claims is not commensurate with the teachings of enablement of the specification.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 90 is rejected under 35 U.S.C. 102(b) as being anticipated by Tenuta *et al.* (2001, Volatile fatty acids in liquid swine manure kill *Verticillium dahliae* microsclerotia. Canadian Journal of Plant Pathology 23, 207.)

The claims are directed to contacting bacteria or fungi that contaminate buildings or post harvest fruit with certain compounds to inhibit their growth.

Tenuta *et al.* teach contacting fungi that contaminate fruit in a closed environment with a composition comprising isobutyric acid See, e.g., Abstract, page 207, col. 2.

A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 [24 USPQ2d 1321] (Fed. Cir. 1992). Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. See *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 [64 USPQ2d 1202] (Fed. Cir. 2002). “Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates.” *Id.* (quoting *MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1365 [52 USPQ2d 1303] (Fed. Cir. 1999). Moreover, “[i]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.” *Id.*; see also *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 [67 USPQ2d 1664] (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing *In re Cruciferous Sprout Litig.*, 301 F.3d at 1351; *MEHL/Biophile*, 192 F.3d at 1366).

It is noted that *V. dahliae* is a fungus that infects at least olives and strawberries postharvest.

Growth of the microbe is inhibited at least to some extent.

As noted in the rejections under 35 U.S.C § 112, *supra*, the metes and bounds of the amounts as claim designated cannot be readily determined, even when reading the claims in light of the specification.

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Claims 90, 92, 97, 98, 99 are rejected under 35 U.S.C. 102(b) as being anticipated by Freytag *et al.* (U.S. Patent No. 3,978,242) in light of Rengpipat *et al.* (Appl. and Environm. Microbiol., 1989, vol. 55, pages 2579-1582) and O'Reilly *et al.* (Appl. and Environm. Microbiol., 2000, vol.66, pages 4890-4896)

The claims are directed to contacting bacteria or fungi that contaminate buildings or post harvest fruit with certain compounds to inhibit their growth.

Freytag *et al.* teach contacting cheddar cheese with a composition comprising at least isobutyric acid, 3-methyl-1-butanol and 2-methyl-1-butanol. See, e.g., Example 4. Cheddar cheese contains at least *Lactobacillus*, as adequately demonstrated by Rengpipat *et al.* (Abstract) and routine contaminants on cheddar cheese are *E. coli*, *S. aureus* and *Penicillium*, as disclosed by O'Reilly *et al.* (See, e.g., page 4891)

A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 [24 USPQ2d 1321] (Fed. Cir. 1992). Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. See *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 [64 USPQ2d 1202] (Fed. Cir. 2002). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates." *Id.* (quoting *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 [52 USPQ2d 1303] (Fed. Cir. 1999). Moreover, "[i]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art." *Id.*; see also *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 [67 USPQ2d 1664] (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing *In re Cruciferous Sprout Litig.*, 301 F.3d at 1351; *MEHL/Biophile*, 192 F.3d at 1366).

It is noted that *Lactobacillus*, *E. coli* and *S. aureus* are bacteria and *Penicillium* is a fungus that infect post-harvest food such as cheese and fruit and may infect buildings.

Growth of the microbes is inhibited at least to some extent.

As noted in the rejections under 35 U.S.C § 112, *supra*, the metes and bounds of the amounts as claim designated cannot be readily determined, even when reading the claims in light of the specification.

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No claim is allowed.

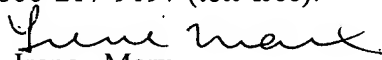
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
Art Unit 1651